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Up-regulating positive affectivity in the transdiagnostic treatment of emotional disorders: a randomized pilot study

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Abstract

Background: Transdiagnostic cognitive behavioral therapy for emotional disorders has proven to be effective. However, current transdiagnostic treatment protocols address only the regulation of negative affectivity, and they do not include treatment components to more directly target the regulation of positive affectivity.

Aims: To evaluate the preliminary efficacy and acceptability of a transdiagnostic treatment protocol for emotional disorders that includes, as an innovative feature, a specific treatment component to directly up-regulate positive affectivity based on positive psychology interventions.

Method: Twenty-four participants were randomized to either a transdiagnostic treatment protocol (N=12) or a transdiagnostic treatment protocol with an additional component designed to regulate positive affectivity (n=12). Participants completed measures of anxiety, depression, positive and negative affectivity, and quality of life, as well as treatment acceptability at pre- and post-treatment and at the 3-month follow-up.

Results: Both interventions led to improvements in all measures at post-treatment, and these outcomes were maintained at the 3-month follow-up, with large effect sizes for all measures. The effect sizes for positive affect were larger in the condition that included the component to up-regulate positive affectivity. Attrition rate was low and both treatment protocols were well-accepted by participants.

Conclusions: The results obtained in this study indicate the feasibility of testing the treatment protocol in a larger, randomized, controlled trial, and they suggest the potential of including treatment components for directly up-regulating positive affectivity in future research on transdiagnostic treatment protocols for emotional disorders.

Keywords: positive affectivity; transdiagnostic; cognitive behavioral therapy; emotional disorders; emotion regulation

Introduction

Emotional disorders (ED) (depression and anxiety disorders) are highly prevalent mental disorders (Kessler et al., 2005; Wittchen et al., 2010) and one of the main causes of disability worldwide (Kazdin, & Blase, 2011; McLean, Asnaani, Litz, & Hofmann, 2011). Currently, there is extensive evidence showing the efficacy and effectiveness of disorder-specific cognitive-behavior therapy (CBT) for several ED, including major depression disorder (MDD) (Cuijpers, Smit, Bohlmeijer, Hollon, & Andersson, 2010; Hollon, & Ponniah, 2010), obsessive-compulsive disorder (OCD) (McKay et al., 2015), and different anxiety disorders, such as generalized anxiety disorder (GAD), panic disorder (PD), agoraphobia (AG), and social anxiety disorder (SAD) (Antony, & Stein, 2009; Barlow, 2002; Nathan, & Gorman, 2007; Olatunji, Cisler, & Deacon, 2010). However, high comorbidity rates among ED (Kessler et al., 2005) have led some researchers to shift the focus to treatment strategies (referred to as transdiagnostic treatments) that might be more widely effective across these diverse mental health problems (Clark, & Taylor, 2009).

To date, there is evidence showing the efficacy of transdiagnostic treatments for anxiety disorders (Reinholt, & Krogh, 2014), and for mixed depression and anxiety disorders (Newby, McKinnon, Kuiken, Gilbody, & Dalgleish, 2015; Păsărelu, Andersson, Nordgren, Dobrean, 2016). An important line of research within the transdiagnostic treatment of ED was initiated by D. H. Barlow (Barlow, Allen, & Choate, 2004). Barlow's theory of triple vulnerability emphasizes the common underlying vulnerabilities in ED and helps to explain the comorbidity among these diverse conditions (Brown, & Barlow, 2009). A central aspect within this theoretical perspective is the role of emotion regulation in ED (Barlow et al., 2004). Emotion regulation has been defined as the attempt to influence the types of emotions people experience, when they experience these emotions, and how these emotions are expressed and experienced (Gross, 1998), with regard to either

negative or positive emotions. Moreover, people can use emotion regulation to up-regulate (increase and/or maintain) or down-regulate (decrease) emotions (Gross, 1998). Difficulties in the regulation of both negative and positive emotions have emerged in research as a common feature in depression and anxiety disorders (Carl, Soskin, Kerns, & Barlow, 2013; Hofmann, Sawyer, Fang, & Asnaani, 2012). The core of these emotion regulation difficulties has been identified as neuroticism or negative affect (N/NA) (Brown, & Barlow, 2009; Barlow, Sauer-Zavala, Carl, Bullis, & Ellard, 2014). However, these deficits have also been associated with low extraversion/positive affect (E/PA). For instance, the association between low PA and several ED, such as unipolar depression (Clark, & Watson, 1991), SAD (Brown, Chorpita, & Barlow, 1998) and AG (Rosellini, Lawrence, Meyer, & Brown, 2010), has been shown in previous research. Additionally, there is evidence indicating that most individuals with anxiety and mood disorders show low levels of PA (Kotov, Gámez, Schmidt, & Watson, 2010). Regarding depression, literature has suggested that there is a link between the maladaptive strategies used by depressed patients to regulate PA and depression symptoms (Gilbert, 2012; Gilbert, Nolen-Noeksema, & Gruber, 2013; Werner-Seidler, Banks, Dunn, & Moulds, 2013), and that deficits in PA regulation are associated with a worse depression prognosis (Shankman, Nelson, Harrow, & Faull, 2011). Finally, a review focused on PA regulation in ED concluded that there are transdiagnostic disturbances in the strategies used to regulate positive emotions that may account for low levels of PA in depression and several anxiety disorders such as GAD, AG, PD, SAD, and OCD (Carl et al., 2013).

The regulation of negative emotions in transdiagnostic models for ED such as the Unified Protocol (UP) has received a great deal of attention in research (Barlow et al., 2013; Ellard, Fairholme, Boisseau, Farchione, & Barlow, 2010). This protocol focuses on four essential aspects that have the general purpose of down-regulating NA: increasing

present-focused emotional awareness, addressing maladaptive emotional avoidance behavior patterns, promoting cognitive flexibility, and facilitating interoceptive and situational exposure. However, although Barlow highlighted the role of low PA in the onset and maintenance of ED (Barlow et al., 2004; Brown, & Barlow, 2009), the main objective of the treatment components in the UP is to train patients in NA regulation, and less attention is paid to the inclusion of treatment components to directly target PA regulation. This is also the case in other empirically evaluated transdiagnostic treatments for anxiety disorders (e. g., Norton, 2012; Titov, Andrews, Johnston, Robinson, & Spence, 2010) and mixed anxiety and depression (e. g., Titov et al., 2011; Berger, Boettcher, & Caspar, 2013).

PA regulation may have important implications in treatment because high PA is associated with better physical and psychological health, healthier lifestyles, and better general functioning (Cohen, & Pressman, 2006; Fredrickson, 2001; Livingstone, & Srivastava, 2012; Pressman, & Cohen, 2005; Quoidbach, Berry, Hansenne, & Mikolajczac, 2010; Tugade, & Fredrickson, 2007). Moreover, the importance of fostering PA, in addition to reducing NA, to improve treatment outcomes in depression and anxiety disorders has been highlighted in the literature (Carl et al., 2013) because high PA seems to promote general well-being, prevent relapses, and produce resilience (Dunn, 2012; Tugade, & Fredrickson, 2007; Wood, & Joseph, 2010).

Positive psychology interventions (PPIs) mainly focus on enhancing positive emotional functioning and wellbeing (Schueller, Kashdan, & Parks, 2014). Schueller & Parks (2014) distinguished five categories under the umbrella of PPIs: a) savoring experiences and sensations; b) cultivating and expressing gratitude; c) engaging in kind actions; d) promoting positive relationship processes; and e) pursuing hope and meaning. Meta-analyses have shown that these interventions are effective for enhancing wellbeing

and reducing depressive symptoms in both the general population and in individuals with a variety of psychosocial problems (Bolier et al. 2013; Schueller, & Parks, 2014; Sin & Lyubomirsky, 2009; Weiss et al., 2016). The addition of PPIs to existing CBT interventions (e.g. transdiagnostic interventions) could help to strengthen their effect on PA, leading to greater and more lasting effects on positive emotional functioning and wellbeing. Taylor, Lyubomirsky, & Stein (2017) recently studied the efficacy of a transdiagnostic intervention based on PPIs for mixed anxiety and depression, reporting significant gains in PA and secondary gains in NA, depression, and anxiety symptoms. However, this study differs from ours in that it does not include strategies for downregulating NA. In regard to this point, the literature has mainly focused on studying the impact of PPIs on depressive symptoms rather than anxiety (see Bolier et al., 2013; Sin & Lyubomirsky, 2009; Weiss et al., 2016). However, research suggests that anxiety disorders may be also appropriate targets for treatments based on PPIs. For instance, AG or SAD have been shown to be characterized by low levels of PA (Brown et al., 1998; Rosellini et al., 2010). Another reason why anxiety disorders may benefit from PPIs is that anxious individuals often engage in strategies that lead to the avoidance of positive experiences and emotions, as outlined in the review by Carl et al. (2013). Accordingly, well-being may be increased in these patients by training them in strategies to up-regulate PA.

Another intervention for depression that can help to promote wellbeing is behavioral activation (Lejuez, Hopko, & Hopko, 2001; Lewinsohn, 1974). From the approach of behavioral activation, depressive symptoms are deemed as the result of decreased levels of activity that lead to a loss of positive reinforcement (Lewinsohn, 1974). The efficacy of behavioral activation in improving wellbeing has been shown in previous research in both depressed (Mazzucchelli, Kane, & Rees, 2009). and non-depressed populations (Mazzucchelli, Kane, & Rees, 2010). Thus, the ability to increase wellbeing

and positive emotion functioning may be strengthen by including behavioral activation procedures in interventions, at least for individuals with depression.

Taking all this into consideration, an important treatment goal from a transdiagnostic treatment approach would be to increase PA while decreasing NA.

Aims

We developed a transdiagnostic protocol (TP) for ED based on the UP (Barlow et al., (2011) and another version of this protocol that also includes a specific component mainly based on PPIs to directly address PA regulation (TP+PA).

Both protocols were tested using a two-armed randomized pilot study. The aim was to assess the differential effect of both interventions on measures of depression, anxiety and quality of life, and on PA and NA. Another goal was to evaluate treatment retention and the acceptability of both interventions by participants. It was hypothesized that: a) both interventions would result in significant improvements on all clinical measures at post-treatment, and these results would be maintained in the short-term (3-month follow-up); b) the TP+PA would significantly outperform the TP group on PA measures; c) acceptability would be high in both conditions, with no statistical differences between conditions.

Method

Procedure

Participants were recruited from individuals seeking treatment at the Emotional Disorders Clinic (Castellon, Spain). After an initial screening assessment that included the administration of a diagnostic interview, participants who met the inclusion criteria were asked to sign a consent form and then randomly assigned to either the TP group or the TP+PA group. Block randomization in blocks of four was performed using a computer-

generated random number sequence. Once participants had been assigned to one of the conditions, they completed pre-treatment primary and secondary outcome measures (self-reported questionnaires). In both groups, the interventions started immediately after pre-treatment assessment. After each treatment session, participants were given a patient treatment handbook and asked to do homework tasks in order to review the specific contents and practice the proposed strategies and skills learned in each session. After completing the treatment protocols, a diagnostic interview and primary and secondary outcome measures were administered to obtain post-treatment data. The assessment instruments were also applied at the 3-month follow-up. All assessments (i.e. diagnostic interviews) were conducted by independent assessors who were blind to the participants' allocation.

The study was registered in Clinicaltrials.gov (https://clinicaltrials.gov/) as NCT02790398 and approved by the Ethics Committee of Universitat Jaume I (Castellon, Spain).

Participants

Twenty-six participants met the inclusion criteria. In the TP+PA group, one participant dropped out after 11 treatment sessions, stating that she had no time to dedicate to the therapy. In the TP group, one participant dropped out after session 5 because she had to move to another city. These participants were excluded from the analyses; therefore, the final sample included 24 participants (see flow of participants in Figure 1).

[Insert Figure 1 about here]

The baseline characteristics of the sample are described in Table 1. Inclusion criteria were as follows: a) being 18 years old or older; b) meeting the DSM-IV (APA, 2000) diagnostic criteria for ED, which included major depression disorder (MDD), dysthymic disorder (DD), generalized anxiety disorder (GAD), social anxiety disorder (SAD), panic disorder (PD), agoraphobia (AG), anxiety disorder not otherwise specified (ADNOS), (unipolar) mood disorder not otherwise specified (MDNOS), and obsessive-compulsive disorder (OCD); and c) ability to understand and read Spanish. Exclusion criteria included: a) schizophrenia, bipolar disorder, or alcohol and/or substance dependence disorder; b) high risk of suicide; c) receiving another psychological treatment during the study; and d) in the case of receiving pharmacological treatment, an increase and/or change in this treatment during the study period (a decrease in pharmacological treatment was accepted).

[Insert table about 1 here]

In the TP group, four participants were taking pharmacological treatment at the time of enrolment. All of them were taking benzodiazepines. In the TP+PA group, three participants were receiving pharmacological treatment at the time of enrolment. Two of them were taking benzodiazepines, and one was taking antidepressants in addition to benzodiazepines. All participants in both conditions decreased the dosage or stopped taking medication during the study. At post-treatment and at the 3-month follow-up, none of the participants were receiving pharmacological treatment.

Measures

Diagnostic measure

Mini International Neuropsychiatric Interview Version 5.0.0 (MINI) (Sheehan et al., 1998). This is a short, structured, diagnostic psychiatric interview that yields key DSM-IV and ICD-10 diagnoses. The MINI can be administered in a short period of time, and clinical interviewers only need brief training. The MINI has been translated into Spanish and validated (Ferrando, Bobes, Gibert, & Lecrubier, 1997).

Self-administered questionnaires

Overall Anxiety Severity and Impairment Scale (OASIS) (Norman et al., 2011). This is a 5-item scale, rated from 0 to 4, that evaluates the frequency, severity, and work, social, academic, and everyday life impairment caused by anxiety symptoms in the past week. The internal consistency of the OASIS has been found to be good (α = .80). The scale has also shown good test-retest reliability (k= .82) and convergent validity. We used the Spanish version of the instrument, which also showed adequate psychometric properties (Mira et al., 2015). In the present study, the Cronbach's alpha for the OASIS was α = .81.

Beck Depression Inventory (BDI-II) (Beck, Steer, & Brown, 1990). It is one of the most widely-used questionnaires to evaluate depression severity in pharmacological and psychotherapy trials. It consists of 21 items about the different symptoms characterizing major depression disorder, added together to obtain the total score, which can yield a maximum of 63 points. The instrument has shown good internal consistency ($\alpha = 0.76$ to 0.95). The Spanish version of this instrument has also shown high internal consistency ($\alpha = 0.87$) in both general and clinical populations ($\alpha = .89$) (Sanz, Navarro, & Vázquez, 2003). In the present study, the Cronbach's alpha for the BDI-II was $\alpha = .92$.

Positive and Negative Affect Scale (PANAS) (Watson, Clark, & Tellegen, 1988).

The PANAS consists of 20 items that evaluate two independent dimensions: positive affect (PA) and negative affect (NA). It contains 10 descriptors evaluating PA (e. g.,

"enthusiastic", "inspired", "proud") and 10 others assessing NA (e. g. "scared", "irritable", "guilty"). The range for each scale (10 items on each) is from 10 to 50 and the patient has to answer how he/she *usually* feels regarding each of these emotions. The scale showed excellent internal consistency (α between .84 and .90) and convergent and discriminant validity. The Spanish version has demonstrated high internal consistency (α = 0.89 and 0.91 for PA and NA in women, respectively, and α = 0.87 and 0.89 for PA and NA in men, respectively) in college students (Sandín et al., 1999). In the present study, the Cronbach's alpha for the PANAS PA was α = .94, and for the PANAS NA, α = .88.

The Quality of Life Inventory (QLI) (Mezzich, Cohen, & Ruiperez, 1996). This is a brief self-report questionnaire that assesses perceived quality of life in different life-related areas. The questionnaire includes 10 items, rated on a scale from one to 10, that assess physical well-being, psychological well-being, self-care and independent functioning, occupational functioning, interpersonal functioning, social emotional support, community and services support, personal fulfillment, spiritual fulfillment, and overall quality of life. The QLI has shown excellent internal consistency (between .90 and .92), test-retest reliability (.87) and discriminant validity. The Spanish validation of the QLI (Mezzich et al., 2000) has also demonstrated good test-retest reliability ($\alpha = .89$) and discriminant validity. In the present study, the Cronbach's alpha for the QLI was $\alpha = .87$.

Acceptability of treatment

Expectations and opinion of treatment Scale. These questionnaires are adapted from Borkovec and Nau (1972). Each scale is made up of 5 items, rated on a scale from 0 (nothing at all) to 10 (completely), that cover how logical the treatment seems to be ("How logical do you think this treatment is?"), to what extent it could satisfy the patient ("How satisfied are you with the treatment?"), whether it could be recommended to a person with

the same problem ("To what extent do you feel confident recommending this treatment to a friend who has the same problems?"), whether it could be used to treat other psychological problems ("To what extent do you think this treatment could be useful in treating other psychological problems?"), and its usefulness for the patient's problem ("To what extent do you think this treatment will be/was helpful to you?"). The expectation scale is applied once the treatment rationale has been explained. Its aim is to measure subjective patient expectations about this treatment. The opinion scale is administered when the patient has completed the treatment, and its aim is to assess satisfaction with this treatment. Our group has used this questionnaire in several research studies (Botella et al., 2007, 2009).

Interventions

Transdiagnostic protocol (TP)

We developed a transdiagnostic protocol for the treatment of ED, adapted from the UP (Barlow et al., 2011) and some of the strategies for emotion regulation from dialectical behavior therapy (DBT) (Linehan, 2003). All the strategies and techniques from the original protocols (UP) have been translated into Spanish, and the contents (e.g. clinical examples) adjusted for cultural differences. The addition of some strategies from DBT (i.e. mindfulness "what" and "how" skills) was considered important because emotion regulation difficulties have been shown to be a key transdiagnostic factor across distinct ED (Campbell-Sills, Barlow, Brown, & Hofmann, 2006; Cisler, Olatunji, Feldner, & Forsyth, 2010) and an important treatment target (Neacsiu, Eberle, Kramer, Wiesmann, & Linehan, 2014). The main differences between the UP and the protocol developed for the present study (TP) are shown in Table 2.

[Insert table 2 here]

The TP is a manualized, structured treatment protocol made up of 12 treatment modules with the general aim of regulating NA (Botella, García-Palacios, Baños, *unpublished manuscript*). These modules are usually administered in 12 to 15 weekly face-to-face sessions (maximum of 18) lasting 60 minutes. Modules 1 to 11 contain strategies for the regulation of NA with the following main therapeutic components from the UP: a) present-focused emotional awareness, b) cognitive flexibility, c) emotion avoidance and emotion-driven behaviors, d) awareness and tolerance of physical sensations, and e) interoceptive and situation-based emotion exposure. Modules 1 to 11 are preceded by three modules (module 1 is an introduction to treatment, module 2 is focused on motivation enhancement, and module 3 provides psychoeducation about emotions) and followed by a relapse prevention module (module 12). The treatment protocol includes one patient handbook and one therapist handbook for each treatment session. In this condition, participants completed a mean of 13.25 sessions (SD = .75) (range 12-14). Modules 1 to 12 are described below:

- Module 1. Introduction to treatment: Provides a framework about the role of
 emotion regulation in emotional disorders. A brief description of the program
 modules is also presented, as well as videos with examples of people suffering
 from different emotional disorders.
- Module 2. Motivation for change and goal setting: The aims are to analyze the advantages and disadvantages of changing, emphasize the importance of being motivated, and highlight the importance of establishing significant life goals.
- Module 3. Understanding the role of emotions: Provides psychoeducation about the adaptive roles and functions of emotions and trains the patient in tracking of emotional experiences using the three-component model of emotions.

- Module 4. Non-judgmental emotional awareness and acceptance of emotional experiences: This module aims to train the patient in non-judgmental emotional awareness (i.e. mindfulness "what" and "how" skills) and in the acceptance of emotional experiences and its importance in the treatment.
- Module 5. Practicing present-focused awareness: The objective is to continue to learn about the acceptance of emotional experiences and increase awareness of physical sensations, thoughts, emotions and daily activities.
- Module 6. Learning to be flexible: It focuses on the importance of maladaptive ways of thinking (i.e. thinking traps) in the maintenance of emotional disorders, and on learning how to identify them.
- Module 7. Practicing cognitive flexibility: This module aims to teach the patients how maladaptive ways of thinking can be modified (i.e. cognitive reappraisal). It also provides information about intrusive thoughts and how to deal with them.
- Module 8. Emotional avoidance: This module aims to teach the patients to identify the emotion avoidance strategies that contribute to the maintenance of ED.
- Module 9. Emotion-Driven Behaviors: The aim is for patients to learn the concept of emotion-driven behaviors (EDB) and replace their own maladaptive EDB with other more adaptive behaviors.
- Module 10. Accepting and facing physical sensations: The objectives are to teach the patients the role of physical sensations in their emotional response and train them in interoceptive exposure, in order to increase tolerance and promote habituation to physical sensations.
- Module 11. Facing emotions in the contexts in which they occur: The purpose is the construction of exposure hierarchies to help the patients begin to face the avoided situations that contribute to the maintenance of the problem.

- Module 12. Relapse prevention: This module aims to review the strategies learned throughout the program, schedule the future practice of the learned strategies, and teach the patient how to identify and cope with future high- risk situations.

Transdiagnostic protocol + Positive affectivity regulation component (TP+PA)

This intervention comprises 16 modules generally delivered in 16 to 19 treatment sessions (maximum of 22). As in the TP, this protocol also includes one patient handbook and one therapist handbook for each module. The structure of this protocol is as follows: a) modules 1 to 11 are the same modules as in the TP; b) modules 12 to 15 constitute a treatment component aimed at the regulation of PA (i.e. enhancement and maintenance of PA); c) module 16 is focused on relapse prevention. In this condition, participants completed a mean of 17.42 sessions (SD = 1.08) (range 16-19). Modules 12 to 15 (PA regulation component) are depicted below:

- Module 12: Learning to move on. This module is focused on the role of behavioral activation, teaching the patient the importance of 'moving on'. Behavioral activation is trained using a diary of daily activities. In order to complete this diary, the patient is provided with monitoring sheets with a scale ranging from 0 to 10 to score both the level of satisfaction with the activities the patient is involved in during the day and to what extent they are linked to his/her personal goals and values. The practice of this exercise is intended to help the patient realize the positive relationship between meaningful activities and mood in order to promote behavioral activation (Lejuez et al., 2001).
- Module 13: Learning to enjoy. This module consists of psychoeducation about the role of positive emotions in life and how to generate and maintain them (e. g. using savoring strategies) (Bryant, 2007). The strategies included in this module are

consistent with Fredrickson's Broaden-and-Build Theory (Fredrickson, 2001), which highlights the effect of positive emotions in broadening intellectual, social and physical resources. The module contains the following techniques:

- The importance of smiling. The week is divided into days when the patient has to smile as much as possible when interacting with other people and days when the patient has to act normally. The effects of "smiling days"/normal "no-smiling days" are discussed with the therapist in the following session.
- Savoring. The patient is asked to engage in everyday activities that he/she normally does fast and without paying attention in a slower and more mindful manner (e.g., eating, taking a shower, walking or driving to work). The patient is then asked to think about how the slow, mindful way of doing these activities makes him/her feel compared to engaging in activities fast and unmindfully.
- Daily time of enjoyment. The patient is encouraged to engage in some pleasant activity on a daily basis (e.g., drinking a cup of coffee or tea, doing sports, listening to music, going for a walk, having a conversation). The patient is also asked to think about how he/she felt during the activity and whether he/she would repeat it again, change it, or add something new to it.
- Module 14: Learning to live. This module is divided into two sections. The first section is focused on the importance of identifying the individual's own psychological strengths. The patients are shown the list of strengths proposed by Peterson & Seligman (2004) (e.g., curiosity, creativity, kindness, self-control, honesty, enthusiasm, equity, respect, gratitude) and asked to choose some of them and think about the ways to promote these strengths. The second section addresses the dimensions of wellbeing identified by Riff (1995, 2014) (e.g. purpose in life, autonomy, personal growth). This section includes an exercise to help the patient select and perform meaningful activities linked to personal values (e.g. for the

- value "being a thoughtful friend": "calling my friends once a week" /"catch up with a friend who I have not seen in a while").
- Module 15: Living and learning. One objective is to practice some exercises to promote emotions linked to wellbeing, such as gratitude (e.g., visit of gratitude, expressing gratitude) (Seligman, Steen, Park, & Peterson, 2005), hope (using an exercise based on the best possible self) (Sheldon & Lyubomirsky, 2006), and curiosity (encouraging the patient's interest in different topics or activities).

 Another aim is to teach the patient to identify episodes of wellbeing and maintain them, using the strategy proposed by Fava (1999) in Well-being therapy, which consists of identifying thoughts and beliefs leading to the premature interruption of wellbeing. The patient is then asked to think about a more realistic way to interpret the situation in order to prolong the feelings of wellbeing as long as possible.

Therapists and treatment fidelity

The treatment protocols were administered by five different therapists working at the Emotional Disorders Clinic at Universitat Jaume I. All therapists but one delivered both protocols (TP and TP+PA). All of them were PhDs or PhD students with three to five years of experience in the diagnosis, psychological assessment and application of CBT for several ED. To ensure treatment fidelity, both therapists and patients were provided with detailed manualized treatment protocols for each of the modules. In addition, therapists they had been previously trained in the application of the treatment manuals, and they were supervised on a weekly basis by expert clinical psychologists, members of our research team who had been involved in the design and development of the treatment protocol.

Statistical methods

All analyses were performed using the software SPSS version 22.0. Descriptive statistics (means and standard deviations) were calculated for all measures. Two-way repeated-measures ANOVAs (time, treatment, treatment x time) were performed to explore the statistical significance of the differences within- and between- subjects on all measures. The magnitude of the intervention was expressed as Hedges' *g*, a variation of Cohen's *d* (Cohen, 1988) that corrects for biases due to small sample sizes (Hedges & Olkin, 1985) and a recommended effect size estimator when sample sizes are lower than 20 (Hunter, & Schmidt, 2004). To interpret effect sizes, Cohen's *d* convention (Cohen, 1988) was used, according to which an effect size of 0.20 is considered small, 0.50 is considered moderate, and 0.80 and above is considered large. Confidence intervals were also calculated for each of the effect sizes.

Because the number of participants who dropped out from both groups is low (one participant in each condition), only completer analyses were performed.

Results

Within and between-group changes in primary and secondary outcomes

Means and standard deviations for both groups before and after the intervention and at the 3-month follow-up are displayed in table 3.

[Insert Table 3 about here]

Within- and between-group effect sizes (Hedges' g), as well as confidence intervals, are displayed in table 4. In general, within-group effect sizes were large to very large for the OASIS, the BDI-II, and the QLI in both treatment groups. Regarding the PANAS +, within-group effect sizes were mainly large in both groups, with overall larger

effect sizes in the TP+PA group than in the TP group at post-treatment and at the follow-up. However, the effect size for the TP group at post-treatment was in the moderate range (g = -.77). For the PANAS -, within-group effect sizes were all in the large range, with slightly larger effect sizes found in the TP+PA group than in the TP group at post-treatment and at the follow-up. Regarding comparisons between conditions (between-group effect sizes), a small effect size was observed at post-treatment and at the follow-up on all measures, including the PANAS +.

[Insert Table 4 about here]

To explore the statistical significance of the treatment gains and the differences between conditions, a two-way repeated-measures ANOVA was performed. The ANOVA showed a significant time effect on all measures: PANAS P ($F_{(1.72,37.88)} = 15.47$, p < .001), PANAS N ($F_{(1.54,33.85)} = 44.13$, p < .001) BDI-II ($F_{(1.22,26.82)} = 49.84$, p < .001) OASIS ($F_{(1.72,37.91)} = 23.25$, p < .001) and QLI ($F_{(1.57,34.57)} = 36.21$, p < .001). The participants significantly improved from pre- to post-treatment on all outcomes, and these improvements were maintained at the 3-month follow-up. Nevertheless, the analysis failed to find a significant interaction effect (time x group) on any of the measures (p > .05). Thus, no significant differences were found between the two groups.

Diagnostic status

Results assessed by the MINI interview showed that 7 participants (58%) in the TP+PA condition and 8 in the TP condition (67%) no longer met the diagnostic criteria for any disorder at post-treatment. At the 3-month follow-up, 8 participants in the TP+PA condition no longer met the diagnostic criteria for any ED (67%), whereas 7 participants in

the TP condition (58%) no longer met these criteria. A chi-square test did not reveal any statistical difference in the proportion of diagnosis-free participants at post-treatment and at follow-up.

Acceptability of the treatment

Means and standard deviations for expectations and opinions about treatment are depicted in Table 6. In the TP+PA condition, results indicate that participants reported high scores on all the items measuring treatment expectations (scores between 7.83 and 8.58): logic of the treatment, satisfaction with the treatment, recommendation of the treatment to other people with similar problems, usefulness of the treatment for other psychological problems, and usefulness of the treatment for one's specific problem. After receiving the intervention, scores for treatment opinions improved compared to scores for treatment expectations (scores between 8.08 and 8.83). Overall, the results for expectations and opinions in the TPP condition were higher than in the TPP+PA condition, ranging between 8.83 and 9.17 for expectations, and between 8.58 and 9.67 for opinions. As indicated by a two-way repeated-measures ANOVA, no significant differences were found between the two groups on any of the items assessing expectations and opinions.

[Insert Table 5 about here]

Discussion

The aim of the present study was to evaluate the feasibility, in terms of preliminary efficacy and acceptability, of a new transdiagnostic treatment protocol for ED that includes a specific therapeutic component to directly up-regulate PA. To do so, two versions of the same protocol were developed and tested in a randomized pilot study. One treatment

protocol includes strategies that focus on the regulation of NA alone (TP), and the other protocol adds these strategies to a treatment component to up-regulate PA (TP+PA). To the best of our knowledge, this is the first study to empirically investigate a transdiagnostic protocol for ED that integrates a specific component to directly up-regulate PA.

One aim was to assess the effect of both interventions on a set of clinical measures. Overall, the analyses showed that both interventions resulted in significant improvements in all measures at post-treatment, and that the clinical gains were maintained at the 3-month follow-up. Both interventions were effective in reducing depression and anxiety, and these gains were maintained at the follow-up assessment. Additionally, both treatment protocols led to significant improvements in quality of life at post-treatment and at the 3-month follow-up. However, the analyses did not reveal any significant differences between-groups on any of the scales.

We were also interested in studying the differential effects of the two interventions on PA. The first hypothesis was that the TP+PA would lead to significantly higher PA outcomes than the TP. The effect sizes for PA were larger in the TP+PA group than in the TP group at post-treatment (g = 1.34 versus g = .77) and at the 3-month follow-up (g = 1.30 versus g = .85). Although not significant, these findings suggest that the inclusion of a treatment component to up-regulate positive affectivity might be important in enhancing PA outcomes. This component has already been empirically tested in a randomized controlled trial (RCT) exploring the efficacy of a web-based intervention for depression (Mira et al., 2017). As in the present study, this RCT examined an intervention that combined CBT techniques (i.e., psychoeducation about emotions, cognitive restructuring, behavioral activation) and PPIs, reporting significant improvements in NA and PA compared to a waitlist control group. Although there is a body of literature on PPIs, it is difficult to relate the results of this study to those of previous meta-analyses (e.g. Bolier et

al., 2013; Sin, & Lyubomirsky, 2009; Weiss et al., 2016) of these types of interventions, mainly because these meta-analyses utilized wellbeing as the outcome measure, rather than PA. Furthermore, the samples included in the aforementioned meta-analyses are rather heterogeneous, making the comparisons between this study and previous research on PPIs even more difficult. In any case, the treatment approach followed in the present work is consistent with recommendations about the importance of wellbeing and positive emotional functioning (Fava, 2016; Hasler, 2016) and the need for further research on these interventions. Finally, although the main focus of this study was on PA, future research should study whether adding treatment components designed to up-regulate PA to transdiagnostic treatments for ED may result in better NA outcomes, compared to treatments where these components are absent. In any case, these results should be interpreted considering the pilot nature of this study.

Regarding diagnostic status, the number of patients who met the diagnostic criteria for a principal disorder decreased at post-treatment, and this proportion was maintained at the 3-month-follow up. There were no significant differences between groups in the number of participants who no longer met the diagnostic criteria for any disorder after the treatment, and these changes were maintained at the follow-up.

Another objective was to explore the participants' acceptability of the intervention. Results showed that participants in both groups had high expectations about the treatment protocol before receiving it. Moreover, after receiving the intervention, scores on their opinions improved compared to scores for treatment expectations. Attrition rate was low in both groups (one patient dropped out in each group), which also suggests the feasibility of this intervention for a sample of patients with ED. Taken together, the results support the acceptability of both interventions. Although the acceptability of the PA regulation component was not specifically assessed in this study, the results for adherence and

acceptability are consistent with those found by Mira et al. (2017) for a web-based intervention for depression that also included the same component based on PPIs.

In summary, these results suggest that both interventions were equally effective for the treatment of several ED. Moreover, acceptability did not differ significantly between conditions, suggesting that both interventions were similarly accepted by participants.

The main strength of this study is the inclusion of a treatment component that directly addresses PA regulation (i.e. by increasing and maintaining PA). This protocol differs from other transdiagnostic treatments in that it addresses the regulation of positive affect in a more direct way, whereas other transdiagnostic treatments only integrate treatment strategies essentially aimed to down-regulate NA (e. g., Ellard et al., 2010; Norton, 2012, Titov, 2011, 2012).

Previous research has proposed some directions to address both the assessment and treatment of PA regulation from a transdiagnostic perspective (e. g. Carl et al., 2013; Carl, Fairholme, Gallagher, Thompson-Hollands, & Barlow, 2014), but this field is quite new, and more research is needed on this topic. Questions remain about the specific contribution of treatment components aimed at PA regulation in transdiagnostic protocols: what the most effective strategies are; in what proportion; how and when each treatment component (regulation of PA and regulation of NA) should be present in transdiagnostic protocols; who this treatment approach might benefit the most (e. g. depression vs. anxiety disorders); and what the incremental effect of these strategies is on other relevant treatment outcomes such as anxious and depressive symptomatology and quality of life.

This study has limitations that bear mention. First, it is a pilot study with a low number of participants and no waiting list control group. Second, the high effect sizes observed in this study must be interpreted in light of the non-significant confidence intervals shown at most measurement points. Third, this study does not allow us to

separate the effects of the NA- and PA-regulation components. Improvements in PA might be partly due to a carry-over effect, as participants underwent the PA-regulation sessions (sessions twelve to fifteen) after eleven sessions of NA regulation (sessions one to eleven), which makes it difficult to draw conclusions about the specific contribution of each of these treatment components. Fourth, although we assessed the effect of the intervention on both positive and negative affect, we did not include any measure focused on the underlying emotion regulation mechanisms that are hypothesized to be responsible for these changes. Five, most of the therapists involved in the study delivered both versions of the treatment (TP and TP+PA) and were not blind to the treatment conditions. Finally, the addition of a treatment component to one of the treatments tested in this study (TP+PA) resulted in a treatment with more sessions in one condition than in the other. For these reasons, future research should focus on exploring to what extent each of the different treatment components accounts for the improvement in measures of PA and NA and other clinical measures. One possible strategy to do so is conducting dismantling studies. Our research group is currently conducting a dismantling study in order to explore the specific contribution of different therapeutic components in the treatment of depression: a protocol that combines different components (i.e., CBT and PPIs), a protocol based on behavioral activation only, and a protocol based on PPIs only (the study protocol can be seen in https://clinicaltrials.gov/show/NCT03159715).

In conclusion, this study represents an attempt to contribute to the existing gap in transdiagnostic treatments for emotional disorders by adding a treatment component that more directly addresses the regulation of PA. Preliminary efficacy and acceptability results indicate that both interventions are feasible to be tested in a larger RCT. Although we were unable to find a significant difference in PA due to the impact of the positive affect regulation component, the results found in this study suggest the potential impact that

including treatment components to directly target PA regulation may have on this temperament dimension.

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Table 1. Description of participants at baseline

| | TP+PA | | TP | | |
|------------------------------|---------------|----|-----------|---------------|--|
| | n | % | n | % | |
| Gender | | | | | |
| Female | 8 | 67 | 11 | 92 | |
| Male | 4 | 33 | 1 | 8 | |
| Age | | | | | |
| Mean (SD) | 31.33 (12.48) | | 27.75 (10 | 27.75 (10.91) | |
| Range | 21-61 | | 18-57 | | |
| Education | | | | | |
| Basic studies | 3 | 25 | 1 | 8 | |
| Medium studies | 7 | 58 | 4 | 33 | |
| Superior studies | 2 | 17 | 7 | 58 | |
| Marital status | | | | | |
| Married/partnered | 6 | 50 | 5 | 42 | |
| Single | 6 | 50 | 6 | 50 | |
| Divorced/Widowed | 0 | 0 | 1 | 8 | |
| Principal diagnostic | | | | | |
| Generalized anxiety disorder | 5 | 42 | 6 | 50 | |
| Major depression disorder | 2 | 17 | 2 | 17 | |
| Agoraphobia | 2 | 17 | 1 | 8 | |
| Panic disorder | 2 | 17 | 1 | 8 | |
| Social anxiety disorder | 1 | 8 | 1 | 8 | |
| Dysthymic disorder | 0 | 0 | 1 | 8 | |
| Number of comorbid diagnoses | | | | | |
| 0 | 7 | 58 | 6 | 50 | |
| 1 | 3 | 25 | 3 | 25 | |
| 2 or more | 2 | 17 | 3 | 25 | |

Note. TP+PA: Transdiagnostic Protocol + Positive Affect regulation component; TP: Transdiagnostic Protocol.

| Table 2. I | Differences | between | the TP | and the UP |
|------------|-------------|---------|--------|------------|
|------------|-------------|---------|--------|------------|

| | UP |
|---|---|
| TP | UP (Barlow et al., 2011) |
| M1. Introduction to treatment | M0. Introduction to treatment |
| M2. Motivation for change and goal setting | M1. Motivation engagement for treatment enhancement |
| M3. Understanding the role of emotions | M2. Psychoeducation and tracking of |
| (psychoeducation about emotions and goal setting) | emotional experiences |
| Component 1: Present-focused emotional | Component 1: Present-focused emotional |
| awareness | awareness |
| M4. Non-judgmental emotional awareness and acceptance of emotional experiences M5. Practicing present-focused awareness: physical sensations, thoughts, emotions and daily activities | M3. Emotion awareness training |
| Component 2: Cognitive Flexibility | Component 2: Cognitive Flexibility |
| M6. Learning to be flexible (identification of thinking traps) M7. Practicing cognitive flexibility (cognitive reappraisal and evaluation of intrusive thoughts) | |
| | |
| Component 3. Emotion avoidance and | Component 3: Emotion avoidance and |
| Component 3: Emotion avoidance and emotion-driven behaviors | |
| emotion-driven behaviors | emotion-driven behaviors |
| | |
| emotion-driven behaviors M8. Emotional avoidance M9. Emotion-driven behaviors | emotion-driven behaviors M5. Emotion avoidance and emotion-driven behaviors |
| emotion-driven behaviors M8. Emotional avoidance | emotion-driven behaviorsM5. Emotion avoidance and emotion-driven |
| emotion-driven behaviors M8. Emotional avoidance M9. Emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations | emotion-driven behaviors M5. Emotion avoidance and emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical |
| emotion-driven behaviors M8. Emotional avoidance M9. Emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations | emotion-driven behaviors M5. Emotion avoidance and emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure |
| emotion-driven behaviors M8. Emotional avoidance M9. Emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M10. Accepting and facing physical | emotion-driven behaviors M5. Emotion avoidance and emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M6. Awareness and tolerance of physical |
| emotion-driven behaviors M8. Emotional avoidance M9. Emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M10. Accepting and facing physical sensations | emotion-driven behaviors M5. Emotion avoidance and emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M6. Awareness and tolerance of physical sensations |
| emotion-driven behaviors M8. Emotional avoidance M9. Emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M10. Accepting and facing physical sensations M11. Facing emotions in the contexts in | emotion-driven behaviors M5. Emotion avoidance and emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M6. Awareness and tolerance of physical sensations M7. Interoceptive and situation-based |
| emotion-driven behaviors M8. Emotional avoidance M9. Emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M10. Accepting and facing physical sensations | emotion-driven behaviors M5. Emotion avoidance and emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M6. Awareness and tolerance of physical sensations |
| emotion-driven behaviors M8. Emotional avoidance M9. Emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M10. Accepting and facing physical sensations M11. Facing emotions in the contexts in | emotion-driven behaviors M5. Emotion avoidance and emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M6. Awareness and tolerance of physical sensations M7. Interoceptive and situation-based |
| emotion-driven behaviors M8. Emotional avoidance M9. Emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M10. Accepting and facing physical sensations M11. Facing emotions in the contexts in which they occur | emotion-driven behaviors M5. Emotion avoidance and emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M6. Awareness and tolerance of physical sensations M7. Interoceptive and situation-based emotion exposures |
| emotion-driven behaviors M8. Emotional avoidance M9. Emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M10. Accepting and facing physical sensations M11. Facing emotions in the contexts in which they occur | emotion-driven behaviors M5. Emotion avoidance and emotion-driven behaviors Components 4 and 5: Awareness and tolerance of physical sensations Interoceptive and situation-based emotion exposure M6. Awareness and tolerance of physical sensations M7. Interoceptive and situation-based emotion exposures M8. Relapse prevention |

Note: A full description of the modules in the UP can be found in Barlow et al. (2011)

Table 3. Descriptive statistics for all measures

| | TP+PA | | | TP | | |
|--------|---------------|--------------|--------------|---------------|--------------|--------------|
| | Pre-T | Post-T | F/U | Pre-T | Post-T | F/U |
| | Mean (SD) | Mean (SD) | Mean (SD) | Mean (SD) | Mean (SD) | Mean (SD) |
| OASIS | 8.50 (3.99) | 1.92 (2.43) | 3.83 (5.04) | 6.75 (3.79) | 1.92 (2.11) | 2.25 (1.82) |
| BDI-II | 20.33 (11.13) | 3.08 (4.30) | 4.92 (6.71) | 15.58 (10.14) | 2.58 (1.93) | 2.75 (2.60) |
| PANAS | 22.83 (7.72) | 32.75 (7.11) | 32.83 (7.66) | 25.58 (7.51) | 31.50 (7.82) | 31.17 (5.54) |
| PA | | | | | | |
| PANAS | 29.83 (8.10) | 14.67 (7.39) | 15.92 (7.39) | 25.25 (7.28) | 14.67 (3.99) | 15.67 (3.70) |
| NA | | | | | | |
| QLI | 5.10 (1.46) | 7.21 (1.11) | 7.40 (1.22) | 5.84 (1.27) | 7.67 (.94) | 7.65 (.80) |

Note. Pre-T: Pre-treatment; Post-T: Post-treatment; F/U: 3-month follow-up. TP+PA: Transdiagnostic Protocol + Positive Affect regulation component; TP: Transdiagnostic Protocol; OASIS: Overall Anxiety Severity and Impairment Scale; BDI-II: Beck Depression Inventory; PANAS +: Positive and Negative Affect Schedule – Positive Affect; PANAS -: Positive and Negative Affect Schedule – Negative Affect; QLI: Quality of Life Inventory

Table 4. Within- and between-group effect sizes for all measures

| | Within-group ([95% CI] | effect size, g | | | Between-gro | oup effect size, g |
|--------|----------------------------|----------------|-------------|--------------|--------------|--------------------|
| | Pre-post | | Pre-F/U | | Post-T | F/U |
| | TP+PA | TP | TP+PA | TP | | |
| OASIS | 1.99 | 1.57 | 1.03 | 1.51 | .00 | .42 |
| | [.96, 2.89] | [.61, 2.43] | [.14, 1.84] | [.56, 2.36] | [80, .80] | [41, 1.21] |
| BDI-II | 2.04 | 1.78 | 1.66 | 1.73 | .15 | .43 |
| | [1.00, 2.95] | [.78, 2.66] | [.68, 2.52] | [.74, 2.60] | [66, .95] | [40, 1.22] |
| PANAS | -1.34 | 77 | -1.30 | 85 | .17 | .25 |
| PA | [-2.17, -0.41] | [-1.57, .08] | [-2.13,38] | [-1.65, .02] | [64, .96] | [56, 1.04] |
| PANAS | 1.96 | 1.80 | 1.79 | 1.66 | .00 | .04 |
| NA | [.93, 2.85] | [.80, 2.68] | [.79, 2.67] | [.93, 2.68] | [80, .80] | [76, .84] |
| QLI | -1.63 | -1.64 | -1.71 | -1.71 | 45 | 24 |
| | [-2.49,66] | [-2.50,66] | [-2.58,72] | [-2.57,72] | [-1.24, .38] | [-1.04, .57] |

Note. Pre: Pre-treatment; Post: Post-treatment; F/U: 3-month follow-up. TP+PA: Transdiagnostic Protocol + Positive Affect regulation component; TP: Transdiagnostic Protocol; OASIS: Overall Anxiety Severity and Impairment Scale; BDI-II: Beck Depression Inventory; PANAS +: Positive and Negative Affect Schedule – Positive Affect; PANAS -: Positive and Negative Affect Schedule – Negative Affect; QLI: Quality of Life Inventory. Positive effect sizes denote a decrease in scores, negative effect sizes denote an increase.

Table 5. Means and standard deviations for expectations and opinion of treatment

| | TP+PA | | TP | | |
|--|--------------|-------------|------------------------|--|--|
| | Expectations | Opinion | Expectations Opinion | | |
| | Mean (SD) | Mean (SD) | Mean (SD) Mean (SD) | | |
| Treatment is | | | | | |
| logical | 7.83 (1.80) | 8.25 (1.82) | 9.08 (.90) 9.42 (.67) | | |
| Satisfaction with | | | | | |
| the treatment | 8.08 (1.73) | 8.08 (2.23) | 9.08 (.79) 9.50 (.67) | | |
| Recommend to | | | | | |
| others | 8.58 (1.38) | 8.83 (1.80) | 9.00 (.95) 9.67 (.65) | | |
| Usefulness for | | | | | |
| other | | | | | |
| psychological | 7.75 (1.06) | 8.17 (1.70) | 8.83 (1.03) 8.58 (.67) | | |
| problems | | | | | |
| Usefulness for one's specific problems | 7.83 (1.70) | 8.25 (1.66) | 9.17 (.94) 9.42 (.79) | | |

Note. Scale ranges from 0 to 10, with higher scores indicating greater satisfaction. TP+PA: Transdiagnostic protocol + Positive affectivity regulation component; TP: Transdiagnostic protocol.